DEPARTMENT OF HEALTH AND HUMAN SERVICES

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JUN 16 2000

Mr. Paul K. Elliott
Manufacturing Manager
Amrex-Zetron, Inc.
641 East Walnut Street
Carson, California 90746

Re: Docket No. 00P-1292
Electrical Muscle Stimulators

Dear Mr. Elliott:

This responds to your citizen petition, dated May 8, 2000, requesting an exemption from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for your firm's patient cables that use a banana style plug. While not specifically stated in your petition, we understand that your patient cable is used with an electrical muscle stimulator. The stated rationale for your petition is that compliance with the performance standard is unnecessary because the banana plug connector is too large to be plugged into an electrical socket or power cord, and the device itself is intended to deliver an electrical shock to the patient.

The FDA Performance Standard adopted the specific requirements in Subclause 56.3(c) of the international electrical safety standard, IEC 60601-1. Enclosed is a copy of pertinent excerpts from that international standard for your reference. It specifies three tests for determining compliance. The lead wire connector that is remote from the patient:

1. shall not come into contact with a flat conductive surface of not less than 100 mm diameter;

2. shall not make electrical contact with a specified test finger (for single pole connectors only); and

3. if able to be plugged into a power outlet (or power cord), shall be protected by insulating means having specified electrical insulation characteristics.

I am denying your petition because your firm's banana style plug fails two of these three tests. While too large to be plugged into a power outlet or power cord, the banana plug is an exposed single-pole connector that can make conductive contact with both a flat conductive surface and with the specified test finger. Both of those requirements address the issue of unintended electrical shock, such as when the patient may inadvertently become grounded. For example, an unintended and unacceptable electrical current could flow to the patient through an attached lead

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wire, if the patient becomes grounded while disconnected from the muscle stimulator. While FDA is most concerned about potentially fatal macro-shock injuries, such as from electrical outlets or power cords, we are also concerned about less serious, but unintended electrical shock hazards. The international standard we adopted addresses both kinds of risk.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Enclosure: As stated